



Docket No: 2685.2001 US2

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: David A. Edwards, Richard P. Batycky, and Lloyd Johnston

Application No.: 10/681,416

Group Art Unit: 1616

Filed: October 8, 2003

Examiner: Mina Haghighatian

Confirmation No.: 7426

Title: HIGHLY EFFICIENT DELIVERY OF A LARGE THERAPEUTIC MASS AEROSOL

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
10-4-04	Hollie Wakefield
Date	Signature
Hollie Wakefield	
Typed or printed name of person signing certificate	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Supplemental Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☐ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☒ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☒ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper. (Filed after payment of issue fee)

10/07/2004 CCHAU1 00000030 10681416 180.00 OP 01 FC:1806

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

(Applies to original applications (other than design) filed on or after May 29, 2000)

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in -§ 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☒ Copies of the cited references **AL3, AM3, AT2 and AU2** are enclosed.
- ☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
- ☒ All cited references are those entered in prior applications, U.S. Application Nos. 09/878,146 and 09/591,307, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
- ☒ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) ☐ under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

The Examiner is requested to return a copy of the list of pending applications indicating which references were considered with the next office communication.


It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☒ [X] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ [] Please charge Deposit Account [] in the amount of [\$]. A copy of this Statement is enclosed.
- ☒ [X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 502807.

Respectfully submitted,

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Dated: 10/4/04

APPLICATION NO.
10/681,416

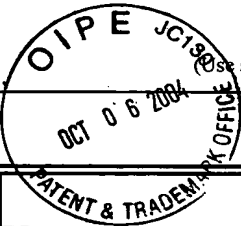
APPLICANT
David A. Edwards *et al.*

FILING DATE
October 8, 2003

CONFIRMATION NO.
7426

GROUP
1616

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REF.
NO.

DOCUMENT NUMBER

ISSUE DATE /
PUBLICATION DATE

NAME

AH4

5,306,483

26 April 1994

Mautone, Alan J.

EXAMINER

DATE CONSIDERED

2685.2001 US2

10/681,416

August 26, 2004

(Use several sheets if necessary)

David A. Edwards *et al.*

October 8, 2003

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AT2

Hanes, J., *et al.*, "Porous Dry-Powder PLGA Microspheres Coated with Lung Surfactant for Systemic Insulin Delivery Via the Lung," *Controlled Release Soc.*, 24:57-58

AU2

Edwards, David A., *et al.* "Large Porous Aerosols for Pulmonary Drug Delivery," *Proc. Int. Symp. Controlled Release Bioact. Mater.*, 24:67-68 (1997)

EXAMINER

DATE CONSIDERED